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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,461	04/17/2001	Robert Leroy Heinrikson	6309.N CP	8815

7590                    06/04/2002

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[REDACTED] EXAMINER

RAO, MANJUNATH N

ART UNIT	PAPER NUMBER
1652	6

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/836,461	HEINRIKSON ET AL.
	Examiner	Art Unit
	Manjunath N Rao	1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2002.
- 2a) This action is **FINAL**.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-45 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20, drawn to polynucleotides, vectors, host cells and method of making the polypeptide, classified in class 435, subclass 69.1.
- II. Claims 21-33, drawn to heparanase polypeptide, classified in class 435, subclass 209.
- III. Claim 34-38, drawn to antibodies and a hybridoma that produces the antibody, classified in class 530, subclass 387.5.
- IV. Claims 39-42, drawn to a method for identification of an agent that alters the heparanase activity, classified in class 435, subclass 18.
- V. Claims 43, drawn to a method of inhibiting the enzymatic activity of an heparanase, classified in class 435, subclass 4.
- VI. Claims 44-45, drawn to a method of treating a disease by administering the antibody, classified in class 424, subclass 94.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, III are patentably distinct from each other. The polynucleotide of group I, the polypeptide of group II, and the antibody of group III, each comprise amino acid sequences and nucleotide sequences which are chemically unrelated, do not require each other for practice; have separate utilities, such as use of the group II polypeptide to catalyze a heparanase reaction versus the use of polynucleotide in a hybridization reaction and are subject to separate

manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions I and IV, V, VI are patentably distinct from each other. The invention of group I is a product which is neither used nor made in the methods of groups, IV-VI. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions II, III and IV, V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of group I can be used for catalyzing a heparanase reaction and the antibody of group III can be used in affinity purification of the polypeptide as opposed to its use in the methods of groups IV and V.

Inventions II and VI are patentably distinct from each other. The invention of group II is a product which is neither used nor made in the method of group VI. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody can be used to affinity purify the polypeptide as opposed to its use in group VI.

Inventions IV, V, VI are patentably distinct from each other. The method of identifying an agent that alters the heparanase activity of group IV, the method of inhibiting the enzymatic activity of group V, the method of treating a disease of group VI are all unrelated as they comprise distinct steps, utilize different products and produce different results. The groups have acquired separate status in the art and separate fields of search as further evidenced by their separate classification.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

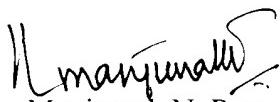
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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath N Rao whose telephone number is 703-306-5681. The examiner can normally be reached on 7.30 a.m. to 4.00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-306-0196.



Manjunath N. Rao  
May 24, 2002